

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING )	)
PHARMACY, INC. PRODUCTS LIABILITY )	)
LITIGATION )	)
----- )	MDL No. 2419
THIS DOCUMENT RELATES TO: )	Dkt. No 1:13-md-2419 (RWZ)
ALL CASES )	)
) )	)

**THE SAINT THOMAS ENTITIES' OPPOSITION TO AMERIDOSE LLC'S MOTION  
FOR PROTECTIVE ORDER AND TO QUASH DEPOSITION NOTICE**

The Saint Thomas Entities<sup>1</sup> file this Opposition to Defendant Ameridose LLC's Motion for Protective Order and Motion to Quash the Deposition Notice to Ameridose LLC (the "Motion") [Docket No. 1879]. This Opposition incorporates by reference the Opposition filed by the Saint Thomas Entities in response to similar motions filed by the Invoking Defendants<sup>2</sup> and Steven Higgins [Docket ## 1869 and 1894].

In support of its Motion, Ameridose LLC ("Ameridose") makes two basic arguments: (1) in light of the fact that all potential witnesses will invoke their Fifth Amendment privilege, it is especially burdensome for Ameridose to comply with its obligations under FED. R. CIV. P. 30(b)(6); and (2) the discovery the Saint Thomas Entities seek from Ameridose is beyond the scope of this Court's Order permitting discovery against Ameridose and other Insider and Related Settling Parties and beyond what is contemplated by the Rules of Civil Procedure.

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<sup>1</sup> Saint Thomas West Hospital f/k/a St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health.

<sup>2</sup> Barry J. Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro, and Glenn A. Chin.

Ameridose is wrong on both counts. As a company, Ameridose was at the epicenter of events leading up to the contamination of methylprednisolone acetate (“MPA”) at NECC that resulted in a nationwide fungal meningitis outbreak. Ameridose’s ownership and management overlapped substantially, if not entirely, with that of NECC. It should not now be heard to claim that it is too far removed from NECC to be troubled with responding to discovery. First, Ameridose has a plain obligation to prepare a witness, even though no employee is currently available for a Rule 30(b)(6) deposition. It cites no case to the contrary. Second, this Court’s Order Limiting Discovery and Staying These Proceedings with Respect to NECC Insiders and Related Settling Parties (the “Order”) [Docket ## 1481, 1482] is clear that the discovery the Saint Thomas Entities seek against Ameridose is permitted. Ameridose has attempted to circumvent the Order by arbitrarily limiting potential liability (and, by extension, discovery in this case) under Tennessee law to “product sellers.” But this is not the law of Tennessee nor the primary basis of the Saint Thomas Entities’ comparative fault claims against Ameridose. Most of the claims pending against the Saint Thomas Entities sound in negligence, and are viable against not just “sellers,” but anyone with a negligence-based duty, including Ameridose. The Saint Thomas Entities are entitled to take Ameridose’s deposition to find out what the company knows, and use that information to prove comparative fault claims against Ameridose and other parties at trial. Given Ameridose’s role in the outbreak and its relationship with NECC, it should be compelled to submit to a deposition.

#### **BACKGROUND**

The Saint Thomas Entities seek the deposition of Ameridose in support of their comparative fault claim against Ameridose asserted in their Master Answer [Docket # 1464, p. 61] and, more generally, because of Ameridose’s central role in the design of NECC’s facility in

Framingham, Massachusetts.<sup>3</sup> Moreover, given the significant overlap in ownership and management between Ameridose and NECC, the Saint Thomas Entities want to ask questions about the circumstances surrounding the contamination of MPA at the NECC facility, the resulting outbreak of fungal meningitis, and the closing of NECC and Ameridose. The answers received in response to questions about these topics will undoubtedly help the Saint Thomas Entities prove comparative fault against Ameridose and other affiliated defendants.

Ameridose, a limited liability company located in Westborough, Massachusetts, was managed by Gregory Conigliaro and Barry Cadden, the former managers of NECC. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose was a “distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future.”

The Saint Thomas Entities are seeking discovery to prove that Ameridose was negligent in its role as NECC’s distribution center and in its participation in the design and management of the cleanrooms in which the contaminated MPA was later compounded. From 2006-2009, Ameridose occupied the facility that NECC occupied in the fall of 2012 when contaminated MPA was compounded by NECC. Documents produced in this litigation reveal that Ameridose communicated extensively with Liberty Industries, Inc. (“Liberty”) in constructing the very cleanroom in which the MPA at issue was compounded. (*See Exhibit 1.*) An automatic pass-through conveyor belt, which is very much at issue in this litigation, was built by Liberty for Ameridose in 2007. Ameridose was heavily involved in the design process, proposing multiple

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<sup>3</sup> Rather than repeat all of the general background facts here, the Saint Thomas Entities again refer the Court to their Opposition to the Invoking Defendants’ Motion for Protective Order [Docket # 1869].

ways to get product out of the NECC cleanroom more quickly. (*See Exhibit 2.*) Moreover, documents show that the management of NECC and Ameridose were intertwined and the two cannot be disentangled; letters were signed by Steve Higgins, Project Manager for “Ameridose/NECC.” (*See Exhibit 3.*) In fact, the close relationship between the companies impacted regulatory decisions at NECC. As a committee report from the United States Congress explains:

Ameridose, had a significant history with FDA. FDA was well aware of the **firms' shared ownership and management**. On several occasions, **this factored into FDA's decision-making** about whether and when to take certain actions related to one of the companies.

*See FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities*, Staff Report, Committee on Energy and Commerce, April 16, 2013, available at <http://docs.house.gov/meetings/IF/IF02/20130416/100668/HHRG-113-IF02-20130416-SD101.pdf>.

The Saint Thomas Entities intend to prove that Ameridose owed a duty to the Plaintiffs in this litigation and breached it. Ameridose’s Motion focuses heavily on the Tennessee Product Liability Act (“TPLA”), and argues that it cannot be subject to discovery because it is not liable under the plain language of the Act as it was not a seller or distributor of the contaminated MPA. Ameridose, however, neglects to mention that the Saint Thomas Entities are seeking to hold Ameridose responsible under a negligence-based theory: that Ameridose’s negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs. (*See Master Answer at ¶ 15.*)<sup>4</sup> This negligence theory—separate and apart from the TPLA—is the heart of the Plaintiffs’ claims against the Saint Thomas Entities and is also the

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<sup>4</sup> Ameridose has never moved to strike this affirmative defense and only now, trying to avoid discovery, argues that it is not viable.

subject of much of the comparative fault discovery that the Saint Thomas Entities are seeking here (such as against discovery against Liberty, who designed the cleanrooms; Unifirst, who was responsible for cleaning them; and GDC, who managed the NECC facility property).

Ameridose is in the same position as these other defendants and should not be given a pass on discovery.<sup>5</sup> In a multi-million dollar settlement with the Trustee, Ameridose specifically sought the benefits of the bankruptcy court-approved plan and was well aware that this Court's Order regarding discovery did not "prohibit defendants from pressing affirmative defenses or claims against individuals or entities other than the Settling Parties, nor does it block discovery relevant to such defenses (including comparative fault or negligence) or claims from the Settling Parties." [Docket # 1481.] Ameridose should not now be heard to complain that the discovery clearly contemplated by the Court's order in October is unnecessary and expensive. The Court should permit the Saint Thomas Entities to take Ameridose's 30(b)(6) deposition.

## **ARGUMENT**

### **I. AMERIDOSE SHOULD NOT BE PERMITTED TO AVOID DISCOVERY IN ITS ENTIRETY SIMPLY BECAUSE ITS OWNERS, MANAGERS, AND AGENTS HAVE FIFTH AMENDMENT CONCERNs.**

Ameridose argues, in essence, that it should not be compelled to submit to a Rule 30(b)(6) deposition because it is too burdensome given that 1) all individuals that have been affiliated with Ameridose will invoke their Fifth Amendment privilege and 2) it is too expensive

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<sup>5</sup> Ameridose's obligations remain the same regardless of whether it is a party or, in the event the cases against it are dismissed, a non-party. Ameridose itself recognizes this in its Motion to Show Cause Why Cases Should Not Be Dismissed [Docket No. 1929, fn. 1], which states: "Importantly, no party in the NECC MDL has standing to object to the dismissal of the cases on Exhibit A. No parties to this MDL objected to the injunction in Bankruptcy Court. Furthermore, under Paragraph 16 of the Plan Confirmation Order and Section 10.07 of the Plan, certain defenses for non-settling MDL defendants based upon comparative fault are preserved to the extent they are available under applicable state law. Therefore, dismissing the cases on Exhibit A will not affect the rights and obligations of the Tennessee Clinic Defendants, the St. Thomas Entities, or any other party attempting to assert certain defenses based upon comparative fault."

and onerous to prepare a witness who does not know anything yet about the company. Not only is Ameridose seeking to avoid a deposition, its papers make plain that is refusing to produce documents as well. According to the Affidavit of Matthew Moriarty, Ameridose has not “processed” its documents and thus, they are not available to any party in this litigation. [Docket # 1879-2, ¶ 8-9.] It claims it will cost over \$1 million to do so, and Ameridose does not want to use any resources to do it. (*Id.*) In other words, Ameridose seeks to ensure that no party has the opportunity to conduct any discovery against it.

Ameridose has an obligation to prepare someone to testify. Under FED. R. CIV. P. 30(b)(6), a designee need not have personal knowledge of the deposition topics. *See* FED. R. CIV. P. 30(b)(6) (“The persons designated must testify about information known or reasonably available to *the organization*.”) (emphasis added). Instead, the corporation must prepare and educate the designee so he or she “can answer fully, completely, [and] unevasively.” *Bridgell v. Saint Gobain Abrasives Inc.*, 233 F.R.D. 57, 60 (D. Mass. 2005) (“If necessary, the deponent must use documents, past employees, and other resources in performing this required preparation.”). Ameridose, while citing many cases holding that specific people may not be compelled to testify (or prepare another to do so) over Fifth Amendment concerns, cites no case holding that a corporation should be relieved of its obligation to testify in these circumstances.

Instead, Ameridose argues that, preparing a witness from scratch, at this point, would be far too onerous because it has not yet processed any documents and to do so would cost in excess of \$1,000,000.00. (*See* Moriarty Aff. at ¶ 9.) Ameridose was aware that this discovery was an issue in October when the Court issued its Order [Docket # 1482]. And, as noted below, this claim is contrary to the parties’ prior discussions and ignores the ESI Protocol the Court has already put into place to address such concerns [Docket #1087]. But such a claim only highlights

the dilemma the Saint Thomas Entities face – not only is Ameridose unwilling to educate a 30(b)(6) witness, they are unwilling to produce any documents to the Saint Thomas Entities. The very company that designed the cleanroom where the contaminated MPA was compounded, the very company that was owned and operated by the same people that owned and operated NECC, all of whom will claim the Fifth Amendment privilege, proposes that no discovery be conducted against it whatsoever. Such an outcome is plainly unfair to the Saint Thomas Entities, who have the right to assert and establish their comparative fault defenses.

With respect to the alleged financial burden Ameridose claims it would suffer if it had to participate in discovery, it is misleading at best. The Court previously entered an ESI Protocol aimed at minimizing the burden of producing electronically stored information through transparency and cooperation. Accordingly, when Ameridose disclosed to the Saint Thomas Entities that it had not processed ***all of the hard drives that exist*** and that doing so would be unduly burdensome and expensive, the Saint Thomas Entities proposed a common sense solution per the ESI protocol:

While we cannot agree at this time to limit search terms to the e-mail server, ***we are open to the discussion.*** In particular, please provide us with an index or listing of the hard drives you possess along with any information you have on the source, custodian and content of each drive ***so that we can determine which of the hard drives the Saint Thomas Entities will agree to exclude from the search terms we hopefully can agree upon.***

(See Exhibit 4) (emphasis added). The Saint Thomas Entities even provided a list of search terms to minimize the cost and burden of the document production. (*Id.*) Ameridose refused to provide any of the information requested or search its e-mail servers, which have already been imaged and are easily searchable. (*Id.*) Ameridose's conduct reflects its goal of avoiding discovery rather than participating in it.

Ameridose should be compelled to comply with the Rules and produce documents and a witness, such as a consultant, as a Rule 30(b)(6) witness. If Ameridose refuses, claiming, in essence, that it is a corporation with a Fifth Amendment privilege, the Saint Thomas Entities should be permitted to seek an adverse inference against Ameridose based on its failure to comply with Rule 30(b)(6). An adverse inference may be appropriate where a corporate defendant fails to offer a witness under Rule 30(b)(6). *See Louis Vuitton Malletier S.A. v. LY USA, Inc.*, 676 F.3d 83, 93, 103 (2d Cir. 2012) (district court did not abuse its discretion in “draw[ing] an adverse inference from corporate defendants’ refusal to submit Rule 30(b)(6) witnesses for depositions”). Similarly, “a court may also grant an adverse inference instruction for the non-production of evidence.” *Hawley v. Mphasis Corp.*, 302 F.R.D. 37, 54-55 (S.D.N.Y. 2014) (adverse inference instruction is appropriate sanction for party’s non-production of records and repeated failure to produce a knowledgeable Rule 30(b)(6) witness). Here, such an instruction is appropriate, particularly in light of Ameridose’s refusal to participate in the ESI Protocol previously ordered by the Court. If Ameridose refuses, despite an order to the contrary, to dedicate the necessary resources to finding and educating a witness, the Saint Thomas Entities should be entitled to an instruction to the jury that it may find that Ameridose would have testified adversely to its interest on all of the topics identified in the Saint Thomas Entities’ deposition notice. Without such an inference, the Saint Thomas Entities are left without any recourse.

**II. THE SAINT THOMAS ENTITIES SEEK COMPARATIVE FAULT DISCOVERY AGAINST AMERIDOSE, WHICH IS CLEARLY PERMISSIBLE UNDER THIS COURT’S ORDER AND THE FEDERAL RULES OF CIVIL PROCEDURE.**

Ameridose further argues that the Saint Thomas Entities seek discovery outside what is permitted by this Court’s Order. That Order allows discovery “relevant to the prosecution, or

defense, or claims against defendants other than the Estate Parties or the Insider Settling Parties. (*See id.*) Ameridose reasons that the Saint Thomas Entities cannot establish fault against Ameridose, as it was neither a “manufacturer” nor a “seller” under the TPLA and therefore “cannot be held liable under Tennessee product liability law.” Given that Ameridose cannot be liable under the TPLA, its argument goes, the discovery the Saint Thomas Entities seek must be beyond the scope of the Order. *See Memo in Support of Motion at 6-13.*

This argument is disingenuous, at best. Plaintiffs have brought a number of causes of action against the Saint Thomas Entities, almost all of them sounding in Tennessee negligence law, *not* the TPLA. The Saint Thomas Entities’ comparative fault defenses are asserted against other parties and non-parties for their common-law negligence, not for their role as “sellers” or “manufacturers” of a defective product under the TPLA.<sup>6</sup> *See McIntyre v. Valentine*, 833 S.W.2d 52, 58 (Tenn. 1992) (holding that when a defendant alleges that another actor “caused or contributed to the injury or damage[,] . . . the trial court shall instruct the jury to assign this [actor] the percentage of the total *negligence* for which he is responsible”) (emphasis added). Indeed, the Saint Thomas Entities’ requests for comparative fault for discovery unquestionably apply to the negligence claims against them; they have sought (and received) discovery from parties such as Unifirst (the company responsible for cleaning the cleanrooms at NECC) and Liberty (the company responsible for building those cleanrooms), which are not “manufacturers” under any stretch of the imagination. Ameridose’s argument that it would be “legally impossible” for a jury to find it was negligent is simply without basis.<sup>7</sup>

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<sup>6</sup> The Saint Thomas Entities, like Ameridose, maintain that they are not product sellers under the TPLA.

<sup>7</sup> Ameridose also argues that if the Saint Thomas Entities’ theory against Ameridose is in strict liability, then Ameridose and NECC will be considered a single share on the verdict slip under the Tennessee Supreme Court’s decision in *Owens v. Truckstops of America*, 915 S.W.2d 420,

Further, this discovery is also relevant to the product liability claims, where the product is listed along with the parties and non-parties. *See Owens v. Truckstops of Am.*, 915 S.W.2d 420, 433 (Tenn. 1996). It is only that portion of the fault allocated to the product that results in joint and several liability among any defendants held liable for the product. *Id.* at n.17. Finally, the Saint Thomas Entities have pled, and are entitled to prove, that the actions of others were the sole cause of the Plaintiffs' injuries. *See* Docket No. 1464, Saint Thomas Entities' Master Answer at p. 52, 55-56 (pleading that it did not "proximately cause any damages alleged by Plaintiffs," which "are the consequence of independent, intervening, and superseding causes, and the acts of third persons," who "caused or contributed to cause the injuries" at issue and should be allocated fault). Thus, the Saint Thomas Entities are well within their rights under the Order to seek the requested discovery from Ameridose.

Moreover, the Saint Thomas Entities seek discovery of Ameridose so they can establish the comparative fault of other parties against which they have asserted comparative fault. While Ameridose argues that "any discovery obtained from [it] is irrelevant to the prosecution or defense, of claims against the Saint Thomas Entities," this argument rings hollow. The activities of Ameridose were so intertwined with those of NECC that *none* of the seven individuals who have been affiliated with Ameridose are willing to testify without invoking his or her Fifth Amendment right. (*See* Moriarty Aff. at ¶¶ 4-6.) If they have Fifth Amendment concerns, then, by definition, they must have been intimately involved with NECC's operations. Ameridose's argument that it is separate and without knowledge of what occurred at NECC is completely

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433 (Tenn. 1996). Regardless of what the court's decision *Owens* actually holds, Ameridose's argument, once again, relies on the erroneous assumption that the Saint Thomas Entities seek to assert fault against it under a products liability theory.

undermined by the assertion that all seven of the individuals affiliated with Ameridose have a legitimate concern that their testimony would incriminate them.

If Ameridose truly has no one to designate without implicating Fifth Amendment concerns, the Saint Thomas Entities request that Ameridose engage a representative, educate him or her (with the help of counsel) by reviewing the available documents, and have that representative answer deposition questions on behalf of the company. Ameridose has been on notice that this discovery was an issue since October and should not now be permitted to hide behind the fact that it does not want to “process” documents and because it has no processed documents, cannot prepare a representative for a deposition. The Court’s Order and the Rules of Civil Procedure require more.

### **CONCLUSION**

For these reasons, the Saint Thomas Entities ask that the Court deny the Motion and require Ameridose to produce a 30(b)(6) witness for deposition and answer questions about the topics outlined in the Notice. If Ameridose refuses to do so, the Saint Thomas Entities request that the Court issue an order finding that Ameridose would have given testimony against its interest in response to all questions posed on the subject contained in the Saint Thomas Entities’ deposition notice.

SAINT THOMAS WEST HOSPITAL,  
FORMERLY KNOWN AS ST. THOMAS  
HOSPITAL, SAINT THOMAS NETWORK,  
AND SAINT THOMAS HEALTH

By their attorneys,

/s/ Sarah P. Kelly

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**CERTIFICATE OF SERVICE**

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 5th day of June, 2015.

*/s/ Sarah P. Kelly*  
SARAH P. KELLY

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